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MRL Changes in Isotianil Fentrazamide and Boscalid

Report Categories:

Sanitary/Phytosanitary/Food Safety

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Report Highlights:

On August 25, 2009, Government of Japan announced proposed changes to the MRLs for Isotianil, Fentrazamide and Boscalid. The domestic comment period has already closed, but MHLW will notify these proposed changes to the WTO/SPS committee, which will provide a chance for public comments to be submitted on this subject.

General Information:

On August 25, 2009, Government of Japan announced proposed changes to the MRLs for Isotianil, Fentrazamide and Boscalid. The domestic comment period has closed already but MHLW will notify these proposed changes to the WTO/SPS committee, which will provide a chance for public comments to be submitted on this subject. After the closing of a the comment period in the WTO, a final report

will be made based on the conclusions of a session of the Pharmaceutical Affairs and Food Sanitation Council slated to be held at a later date; this will constitute the final decision.

This change was announced by the following office:

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Pesticides and Other Contaminants:

Establishment of Maximum Residue Limits for Agricultural Chemicals in Food

Purpose and Background

The Ministry of Health, Labour and Welfare (MHLW) is developing the compositional specification for food.

Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the MHLW is authorized to establish residue standards (maximum residue limits: MRLs) for pesticides, feed additives, and veterinary drugs (hereafter referred to as just “agricultural chemicals”) that may remain in foods. Any food for which standards are established pursuant to the provisions is not permitted to be marketed in Japan unless such food complies with the established standards.

On May 29, 2006, the MHLW introduced the positive list system for agricultural chemicals in food.* Basically, all foods distributed in the Japanese marketplace are subject to regulation based on the system.

This time the MHLW has newly established MRLs (draft) for some food commodities as well as has comprehensively reviewed the current MRLs. This activity is targeted to three chemicals: Isotianil (pesticide), Fentrazamide (pesticide) and Boscalid (pesticide). Details are given below.

Note: The positive list system was established based on the 2003 amendment of the Food Sanitation Law. The system aims to prohibit the distribution of any food in the Japanese marketplace if it contains agricultural chemicals at amounts exceeding a certain level (0.01 ppm) specified under the Law.

Outline of revision

Isotianil (fungicide): This chemical is not permitted for use in Japan. This time the Ministry of Agriculture, Forestry and Fisheries (MAFF) has decided to approve the chemical based on the Agricultural Chemicals Regulation Law. In response to the MAFF's action, the MHLW has newly established MRLs (draft) for some crops. Currently, MRLs are not set for any crops. For draft MRLs, see Attachment 1-1.

Fentrazamide (herbicide): This chemical is already permitted for use in Japan. The MHLW has newly established a MRL (draft) for the "aquatic animals" category and has comprehensively reviewed the existing MRLs. For draft MRLs, see Attachment 1-2.

Boscalid (fungicide): This chemical is already permitted for use in Japan. This time MAFF will expand the scope of target crops for which the use of the chemical is permitted. Also, an application has been filed by a foreign business with the MHLW for the establishment of MRLs for this chemical, based on the Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan, published on 5 February 2004. In response to the MAFF's action and the manufacture's application, the MHLW has newly established MRLs (draft) for some crops and comprehensively reviewed the existing MRLs. For draft MRLs, see Attachment 1-3.

Isotianil (fungicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Rice (brown rice)	0.3	

The uniform limit (0.01 ppm) is applied to commodities for which draft MRLs are not given.
Attachment 1-2

Fentrazamide (herbicide)

Commodity	MRL (draft) ppm	Current MRL※ ppm
Rice (brown rice)	0.02	0.1
Fish and shellfish	0.03	

The uniform limit (0.01 ppm) is applied to commodities for which draft MRLs are not given.
Draft MRLs for fentrazamide are established for the residue of fentrazamide alone.

※ Current MRLs for fentrazamide indicate the sum of residues of fentrazamide and CPT(1-(2-chlorophenyl)-4,5-dihydro-1*H*-tetrazole-5-one).

Attachment 1-3

Boscalid (fungicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Barley	3	
Soybeans, dry	2	0.1
Beans, dry ¹	2.5	2.5
Peas	2.5	2.5
Broad beans	2.5	2.5
Peanuts, dry	0.05	0.05
Other legumes/pulses ²	2.5	2.5
Potato	0.05	0.05
Taro	0.05	0.05
Sweet potato	0.05	0.05
Yam	0.05	0.05
Other potatoes ³	0.05	0.05
Turnip, leaves	10	10
Horseradish	0.7	0.7
Chinese cabbage	3.0	3.0
Cabbage	3.0	3.0
Brussels sprouts	3.0	3.0
Kale	18	18
<i>Komatsuna</i> (Japanese mustard spinach)	18	18
<i>Kyona</i>	18	18
Qing-geng-cai	18	18
Cauliflower	3.0	3.0
Broccoli	3.0	3.0
Other cruciferous vegetables ⁴	18	18
Burdock	0.7	0.7

Salsify	0.7	0.7
Lettuce (including cos lettuce and leaf lettuce)	20	11
Other composite vegetables ⁵	2	0.7
Onion	3.0	3.0
Welsh (including leek)	3.0	3.0
Garlic	3.0	3.0
Nira	3.0	3.0
Other liliaceous vegetables ⁶	3.0	3.0
Carrot	0.7	0.7
Parsnip	0.7	0.7
Celery	25	
Other umbelliferous vegetables ⁷	0.7	0.7
Tomato	5	5
Pimiento (sweet pepper)	10	10
Egg plant	2	2
Other solanaceous vegetables ⁸	15	1.2
Cucumber (including gherkin)	5	5
Pumpkin (including squash)	1.6	1.6
Oriental pickling melon (vegetable)	1.6	1.6
Water melon	1.6	1.6
Melons	1.6	1.6
Makuwauri melon	1.6	1.6
Other cucurbitaceous vegetables ⁹	1.6	1.6
Bamboo shoots	1.6	1.6
Ginger	0.05	0.05
Peas, immature (with pods)	5	1.6
Kidney beans, immature (with pods)	1.6	1.6
Green soybeans	2.0	2.0
Other vegetables ¹⁰	1.6	1.6

Boscalid(Continued)

Commodity	MRL (draft) ppm	Current MRL ppm
<i>Unshu</i> orange, pulp	1	1
Citrus natsudaikai, whole	10	10
Lemon	10	10
Orange (including navel orange)	10	10
Grapefruit	10	10
Lime	10	10
Other citrus fruits ¹¹	10	10
Apple	3.0	3.0
Japanese pear	3.0	3.0
Pear	3.0	3.0

Quince	3.0	3.0
Loquat	3.0	3.0
Peach	0.2	1.7
Nectarine	3	1.7
Apricot	3	1.7
Japanese plum (including prune)	3	1.7
Mume plum	3	
Cherry	3	3
Strawberry	15	15
Raspberry	3.5	3.5
Blackberry	3.5	3.5
Blueberry	3.5	3.5
Huckleberry	3.5	3.5
Other berries ¹²	3.5	3.5
Grape	10	10
Japanese persimmon	1	
Banana	0.2	
Other fruits ¹³	1.2	1.2
Sunflower seeds	0.60	0.60
Rapeseeds	3.5	3.5
Ginkgo nut	0.05	
Chestnut	0.70	0.70
Pecan	0.70	0.70
Almond	0.70	0.70
Walnut	0.70	0.70
Other nuts ¹⁴	1	0.70
Coffee beans	0.05	
Hop	35	35
<i>Unshu</i> orange, peel		40
Other spices ¹⁵ (except <i>Unshu</i> orange, peel)		2.5
Other spices	40	
Spearmint		30
Peppermint		30
Other herbs ¹⁶ (except spearmint and peppermint)		18
Other herbs	30	
Cattle, muscle	0.10	0.10
Pig, muscle	0.05	0.05
Sheep, muscle	0.10	0.10
Horse, muscle	0.10	0.10
Goat, muscle	0.10	0.10
Other terrestrial mammals ¹⁷ , muscle	0.05	0.05

Boscalid(Continued)

Commodity	MRL (draft)	Current MRL
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	ppm	ppm
Cattle, fat	0.30	0.30
Pig, fat	0.10	0.10
Sheep, fat	0.30	0.30
Horse, fat	0.30	0.30
Goat, fat	0.30	0.30
Other terrestrial mammals, fat	0.1	0.1
Cattle, liver	0.35	0.35
Pig, liver	0.10	0.10
Sheep, liver	0.35	0.35
Horse, liver	0.35	0.35
Goat, liver	0.35	0.35
Other terrestrial mammals, liver	0.05	0.05
Cattle, kidney	0.35	0.35
Pig, kidney	0.10	0.10
Sheep, kidney	0.35	0.35
Horse, kidney	0.35	0.35
Goat, kidney	0.35	0.35
Other terrestrial mammals, kidney	0.05	0.05
Cattle, edible offal ¹⁸	0.35	0.35
Pig, edible offal	0.10	0.10
Sheep, edible offal	0.35	0.35
Horse, edible offal	0.35	0.35
Goat, edible offal	0.35	0.35
Other terrestrial mammals, edible offal	0.05	0.05
Milk	0.10	0.10
Chicken, muscle	0.05	0.05
Chicken, fat	0.05	0.05
Chicken, liver	0.10	0.10
Chicken, kidney	0.10	0.10
Chicken, edible offal	0.10	0.10
Chicken, eggs	0.02	0.02
Peanut oil (limited to refined peanut oil and peanut salad oil that meet the Japanese Agricultural Standards (JAS) for Edible Vegetable Fats and Oils, and other edible oils that meet standards equivalent to or stricter than JAS)	0.15	0.15
Rapeseed oil (limited to refined rapeseed oil and rapeseed salad oil that meet the JAS for Edible Vegetable Fats and Oils, and other edible oils that meet standards equivalent to or stricter than JAS)	5.0	5.0
Grape, dried	10	8.5

The uniform limit (0.01 ppm) is applied to commodities for which draft MRLs are not given. MRLs for boscalid are established for the sum of residues of boscalid, its metabolites 2-chloro-*N*-(4'-chloro-5-hydroxy-biphenyl-2-yl) nicotinamide and glucuronic acid conjugate of 2-chloro-*N*-(4'-chloro-5-hydroxy-biphenyl-2-yl)nicotinamide, all calculated as boscalid on animal products, and for the sum of the residue of boscalid alone on other foods.

The draft MRLs for "other spices" apply to "*Unshu* orange, peel" and "other spices (except *Unshu* orange, peel)" after revision.

The draft MRLs for "other herbs" apply to "spearmint", "peppermint" and "other herbs (except spearmint and peppermint)" after revision.

Note:

1. "Beans (dry)" includes butter beans, cowbeans (red beans), lentil, lima beans, pegia, sultani, sultapya, and white beans.
2. "Other legumes/pulses" refers to all legumes/pulses, except soybeans (dry), beans (dry), peas, broad beans, peanuts (dry), and spices.
3. "Other potatoes" refers to all potatoes, except potato, taro, sweet potato, yam, and konjac.
4. "Other cruciferous vegetables" refers to all cruciferous vegetables, except Japanese radish roots and leaves (including radish), turnip roots and leaves, horseradish, watercress, Chinese cabbage, cabbage, brussels sprouts, kale, *komatsuna* (Japanese mustard spinach), *kyona*, qing-geng-cai, cauliflower, broccoli, and herbs.
5. "Other composite vegetables" refers to all composite vegetables, except burdock, salsify, artichoke, chicory, endive, *shungiku*, lettuce (including cos lettuce and leaf lettuce), and herbs.
6. "Other liliaceous vegetables" refers to all liliaceous vegetables, except onion, welsh (including leek), garlic, *nira*, asparagus, multiplying onion, and herbs.
7. "Other umbelliferous vegetables" refers to all umbelliferous vegetables, except carrot, parsnip, parsley, celery, *mitsuba*, spices, and herbs.
8. "Other solanaceous vegetables" refers to all solanaceous vegetables, except tomato, pimiento (sweet pepper), and egg plant.
9. "Other cucurbitaceous vegetables" refers to all cucurbitaceous vegetables, except cucumber (including gherkin), pumpkin (including squash), oriental pickling melon (vegetable), watermelon, melons, and *makuwauri* melon.
10. "Other vegetables" refers to all vegetables, except potatoes, sugar beet, sugarcane, cruciferous vegetables, composite vegetables, liliaceous vegetables, umbelliferous vegetables, solanaceous vegetables, cucurbitaceous vegetables, spinach, bamboo shoots, okra, ginger, peas (with pods, immature), kidney beans (with pods, immature), green

soybeans, mushrooms, spices, and herbs.

11. "Other citrus fruits" refers to all citrus fruits, except *unshu* orange (pulp), citrus *natsudaidai* (pulp), citrus *natsudaidai* (peel), citrus *natsudaidai* (whole), lemon, orange (including navel orange), grapefruit, lime, and spices.

12. "Other berries" refers to all berries, except strawberry, raspberry, blackberry, blueberry, cranberry, and huckleberry.

13. "Other fruits" refers to all fruits, except citrus fruits, apple, Japanese pear, pear, quince, loquat, peach, nectarine, apricot, Japanese plum (including prune), mume plum, cherry, berries, grape, Japanese persimmon, banana, kiwifruit, papaya, avocado, pineapple, guava, mango, passion fruit, date and spices.

14. "Other nuts" refers to all nuts, except ginkgo nut, chestnut, pecan, almond and walnut.

15. "Other spices" refers to all spices, except horseradish, *wasabi* (Japanese horseradish) rhizomes, garlic, peppers chili, paprika, ginger, lemon peels, orange peels (including navel orange), *yuzu* (Chinese citron) peels and sesame seeds.

16. "Other herbs" refers to all herbs, except watercress, *nira*, parsley stems and leaves, celery stems and leaves.

17. "Other terrestrial mammals" refers to all terrestrial mammals, except cattle and pig.

18. "Edible offal" refers to all edible parts, except muscle, fat, liver, and kidney.